

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Steven K. Burke

Application No.: 10/686,808

Group Art Unit: 1646

Filed: October 16, 2003

Examiner: Not Yet Assigned

Confirmation No.: 8791

Title: METHOD FOR PROMOTING BONE FORMATION

| CERTIFICATE OF MAILING OR TRANSMISSION | |
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| I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on: | |
| <u>5/20/04</u> Date | <u>Rachel Meehan</u> Signature |
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INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

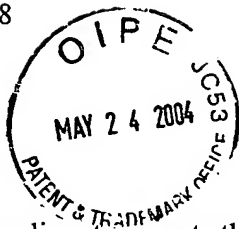
Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☒ Copies of the cited references are enclosed.
- ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
- ☒ The listed references (AL, AM & AR-AT) were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☐ the enclosed English language abstract.



☐ Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

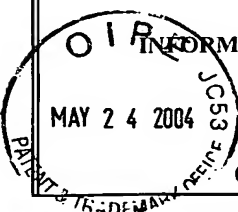
Respectfully submitted,

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Dated: 5-20-04

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| PTO-1449 REPRODUCED | | ATTORNEY DOCKET NO. 1932.2135-002 | | APPLICATION NO. 10/686,808 | |
|  <p>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</p> <p>May 11, 2004</p> <p>(Use several sheets if necessary)</p> | | FIRST NAMED INVENTOR Steven K. Burke | | FILING DATE October 16, 2003 | |
| | | EXAMINER Not Yet Assigned | | CONFIRMATION NO. 8791 | |

U.S. PATENT DOCUMENTS

| EXAM- INER INI- TIAL | REF. NO. | DOCUMENT NUMBER Number-Kind Code (if known) | ISSUE DATE / PUBLICATION DATE MM-DD-YYYY | NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT |
|-------------------------------|-------------|--|--|--|
| | AA2 | US 2002/0051822 A1 | 05-02-2002 | Atherton <i>et al.</i> |
| | AB | 5,487,888 | 01-30-1996 | Mandeville, III <i>et al.</i> |
| | AC | 5,496,545 | 03-05-1996 | Holmes-Farley <i>et al.</i> |
| | AD | 5,607,669 | 03-04-1997 | Mandeville, III <i>et al.</i> |
| | AE | 5,618,530 | 04-08-1997 | Mandeville, III <i>et al.</i> |
| | AE | 5,624,963 | 04-29-1997 | Mandeville, III <i>et al.</i> |
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| | AI | 5,703,188 | 12-30-1997 | Mandeville, III <i>et al.</i> |
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| | AD2 | 6,177,478 | 01-23-2001 | Holmes-Farley <i>et al.</i> |
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| | AJ2 | US 2002/0159968 A1 | 10-31-2002 | Petersen <i>et al.</i> |
| | AK2 | US 2003/0086898 A1 | 05-08-2003 | Holmes-Farley <i>et al.</i> |
| | AA3 | US 2003/0133902 A1 | 07-17-2003 | Holmes-Farley <i>et al.</i> |
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| | AD3 | US 2002/0182168 A1 | 12-05-2002 | Holmes-Farley <i>et al.</i> |

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|-------------------------------|-------------|--|--|--|
| | AE3 | 6,566,407 | 05-20-2003 | Holmes-Farley <i>et al.</i> |
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| | AH3 | US 2002/0187120 A1 | 12-12-2002 | Burke |
| | AI3 | US 2003/0049226 A1 | 03-13-2003 | Burke <i>et al.</i> |
| | AJ3 | US 2003/0039627 A1 | 02-27-2003 | Holmes-Farley <i>et al.</i> |
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| | | DOCUMENT NUMBER Country Code-Number-Kind Code (if known) | DATE MM-DD-YYYY | NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT | TRANSLATION YES NO | |
|--|----|--|--------------------|--|-----------------------|--|
| | AL | WO 03/057225 A2 | 07-17-2003 | Genzyme Corporation | | |
| | AM | WO 93/04373 | 03-04-1993 | NPS Pharmaceuticals, Inc. | | |
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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| | AR | Moe, S., <i>et al.</i> , "Sevelamer HCL Improves Parathyroid Hormone (PTH) and Bone Function in Peritoneal Dialysis (PD) Patients With Probable Low Turnover Bone Disease," <i>American J. of Kidney Diseases</i> , 37(4): A25 (abstract only-Tenth Annual Clinical Nephrology Meeting Abstracts), (2001). |
| | AS | Raggi, P., <i>et al.</i> , "Sevelamer Preserves and Calcium Reduces Trabecular Bone Mineral Density," <i>J. American Society of Nephrology</i> , 14: 502A (abstract only), (2003). |
| | AT | Katsumata, K., <i>et al.</i> , "Sevelamer Hydrochloride Prevents Ectopic Calcification and Renal Osteodystrophy in Chronic Renal Failure Rats," <i>Kidney International</i> , 64: 441-450 (2003). |
| | AU | Slatopolsky, E.A., <i>et al.</i> , "RenaGel®, a Nonabsorbed Calcium- and Aluminum-Free Phosphate Binder, Lowers Serum Phosphorus and Parathyroid Hormone," <i>Kidney International</i> , 55: 299-307 (1999). |

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| AV | Chertow, G.M., <i>et al.</i> , "Sevelamer With and Without Calcium and Vitamin D: Observations From a Long-Term Open-Label Clinical Trial," <i>J. Of Renal Nutrition</i> , 10(3): 125-132 (2000). |
| AW | Chertow, G.M., <i>et al.</i> , "Hyperparathyroidism and Dialysis Vintage," <i>Clinical Nephrology</i> , 54(4): 295-300 (2000). |
| AX | Malluche, H.H., and Mawad, H., "Management of Hyperphosphataemia of Chronic Kidney Disease: Lessons From the Past and Future Directions," <i>Nephrol. Dial. Transplant.</i> , 17: 1170-1175 (2002). |
| AY | Cannata-Andía, J.B., and Rodríguez-García, M., "Hyperphosphataemia as a Cardiovascular Risk Factor -How to Manage the Problem," <i>Nephrol. Dial. Transplant.</i> , 17(Suppl. 11): 16-19 (2002). |
| AZ | Nolan, C.R., and Qunibi, W.Y., "Calcium Salts in the Treatment of Hyperphosphatemia in Hemodialysis Patients," <i>Current Opinion in Nephrology and Hypertension</i> , 12: 373-379 (2003). |
| AR2 | Čizman, B., "Hyperphosphataemia and Treatment With Sevelamer in Haemodialysis Patients," <i>Nephrol. Dial. Transplant.</i> , 18(Suppl. 5): v47-v49 (2003). |
| AS2 | Coco, M., and Rush, H., "Increased Incidence of Hip Fractures in Dialysis Patients With Low Serum Parathyroid Hormone," <i>Am. J. Kidney Diseases</i> , 36(6): 1115-1121 (2000). |
| AT2 | Taal, M.W., <i>et al.</i> , "Risk Factors for Reduced Bone Density in Haemodialysis Patients," <i>Nephrol. Dial. Transplant.</i> , 14: 1922-1928 (1999). |
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| AW2 | Cozzolino, M., <i>et al.</i> , "Role of Calcium-Phosphate and Bone-Associated Proteins on Vascular Calcification in Renal Failure," <i>J. Am. Soc. Nephrol.</i> , 12: 2511-2516 (2001). |
| AX2 | Loghman-Adham, M., "Phosphate Binders for Control of Phosphate Retention in Chronic Renal Failure," <i>Pediatr. Nephrol.</i> , 13: 701-708 (1999). |
| AY2 | Elder, G., "Pathophysiology and Recent Advances in the Management of Renal Osteodystrophy," <i>J. Bone and Mineral Research</i> , 17(12): 2094-2105 (2002). |

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| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | |
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| AZ2 | Bardin, T., "Musculoskeletal Manifestations of Chronic Renal Failure," <i>Curr. Opin. Rheumatol.</i> , 15: 48-54 (2003). | |
| AR3 | Albaaj, F., and Hutchison, A.J., "Hyperphosphataemia in Renal Failure (Causes, Consequences and Current Management)," <i>Drugs</i> , 63(6): 577-596 (2003). | |
| AS3 | Martin, C.J., and Reams, S.M., "The Renal Dietitian's Role in Managing Hyperphosphatemia and Secondary Hyperparathyroidism in Dialysis Patients: A National Survey," <i>J. Renal Nutrition</i> , 13(2): 133-136 (2003). | |
| AT3 | Fontaine, M.A., <i>et al.</i> , "Fracture and Bone Mineral Density in Hemodialysis Patients," <i>Clinical Nephrol.</i> , 54(3): 218-226 (2000). | |
| AU3 | Kleinpeter, M.A., "Spectrum of Complications Related to Secondary Hyperparathyroidism in a Peritoneal Dialysis Patient," <i>Advances in Peritoneal Dialysis</i> , 16: 286-290 (2000). | |
| AV3 | Chertow, G.M., <i>et al.</i> , "Poly(allylamine hydrochloride) (RenaGel®): a noncalcemic phosphate binder for the treatment of hyperphosphatemia in chronic renal failure," <i>Am. J. Kid. Dis.</i> , 29: 66-71 (1997). | |
| AW3 | Goldberg, D.I., <i>et al.</i> , "Effect of RenaGel, a non-absorbed, calcium-and aluminum-free phosphate binder, on serum phosphorus, calcium, and intact parathyroid hormone in end-stage renal disease patients," <i>Nephrol. Dial. Transplant.</i> , 13: 2303-2310 (1998). | |
| AX3 | Chertow, G.M., <i>et al.</i> , "A randomized trial of sevelamer hydrochloride (RenaGel®) with and without supplemental calcium. Strategies for the control of hyperphosphatemia in hemodialysis patients," <i>Clin. Nephrol.</i> , 51: 18-26 (1999). | |
| AY3 | Bleyer, A.J., <i>et al.</i> , "A comparison of the calcium-free phosphate binder sevelamer hydrochloride with calcium acetate in the treatment of hyperphosphatemia in hemodialysis patients," <i>Am. J. Kid. Dis.</i> , 33: 694-701 (1999). | |
| AZ3 | Chertow, G.M., <i>et al.</i> , "Long-term effects of sevelamer hydrochloride on the calcium x phosphorus product and lipid profile of haemodialysis patients," <i>Nephrol. Dial. Transplant.</i> , 14: 2907-2914 (1999). | |
| AR4 | Chertow, G.M., <i>et al.</i> , "Sevelamer attenuates the progression of coronary and aortic calcification in hemodialysis patients," <i>Kidney Int.</i> , 62: 245-252 (2002). | |
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